

INDWELLING URINARY CATHETERIZATION ASSEMBLY

[0001] This application claims priority to U.S. Provisional Patent Application Ser. No. 60/780,972, filed Mar. 10, 2006, the content of which is hereby incorporated by reference in its entirety into this disclosure.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present disclosure is directed to devices and methods for catheterization of the urinary bladder. More particularly, the present invention relates to devices and methods for extended or long-term catheterization of the urinary bladder.

[0004] 2. Background of the Invention

[0005] The occasional or periodic catheterization of an individual's urinary bladder is a common practice today for many persons who are in a hospital setting, a nursing home, doctor's office, rehabilitation facility, or at home. For instance, a patient may be catheterized to treat such conditions as urinary retention, the inability to evacuate urine, or for the purpose of obtaining a sterile urine specimen from a patient in a doctor's office. Some catheterizations may be intermittent or repeated, while other catheterizations may be extended, or long-term. Extended catheterizations may require the use of an indwelling (e.g., "Foley") catheter.

[0006] Generally, catheterizations may be assisted (non self-catheterizations) or unassisted (self-catheterizations). In assisted catheterizations, it is commonplace for a nurse to perform the catheterization procedure using pre-assembled kits, or catheterization tray ("cath tray"), which typically includes a catheter, a drape, disposable gloves, antiseptic solution, cotton balls, a sealed packet containing sterile lubricating jelly, forceps, waterproof absorbent underpad, prepping cotton balls, a sterile urine specimen bottle, and a urine collection container. In particular, for long-term catheterizations, the catheter provided in the cath tray is typically an indwelling catheter capable of being sufficiently maintained within the patient for an extended period of time. All of these items are typically packaged together and sterilized.

[0007] To perform the typical catheterization, the nurse opens the tray, dons sterile gloves and places the drape around the patient's genitalia. The antiseptic solution is opened and poured over the cotton balls. The packet of lubricating jelly is opened and squeezed onto a sterile field. The patient's urethral opening is cleansed with the saturated cotton balls, the nurse holding each with the forceps. The nurse then runs the tip end of the catheter, comprising the first inch or two (about 2.5 cm to about 5 cm) of the insertable portion, through the lubricating jelly. The catheter is then inserted into the urethra and advanced until urine begins to flow. The urine is drained into the urine collection container. A urine specimen may be caught in the specimen bottle, if needed. For long-term catheterizations, a band around the tip of the indwelling catheter may be expanded such that the catheter may not be easily pulled from the bladder and is thus sufficiently maintained in the patient for an extended period of time. This basic procedure is widely used in inpatient hospitals around the world, and has remained essentially the same for 50 years.

[0008] Although the catheterization kit may be sterile prior to opening, the nurse must open the tray and handle the various items in the tray in order to use the kit. Further, even if special precautions are taken, maintaining a "sterile" environment during the procedure may present challenges. Non-sterile techniques and/or contamination of the catheter may result in infection of the patient's urinary tract. In some instances, urinary tract infections may lead to morbidity and additional costs to the patient and society.

[0009] In addition to sanitation concerns, because multiple steps are involved to perform the procedure (e.g., sterilization, lubrication, insertion, etc.), a nurse may spend a significant amount of time (e.g., 10 minutes or more) carrying out each catheterization. Further, the "cath tray" procedure maybe expensive or otherwise impractical for use with some individuals and situations today.

[0010] A variety of catheterization kits and products are currently available. For instance, U.S. Pat. No. 6,090,075 (House I) discloses a catheterization kit including a catheter comprising a rigid introducer member for positioning catheter assembly against the urethral opening, a flexible catheter, and a flexible thin-walled sheath surrounding the catheter and partially covering the catheter introducer.

[0011] Some catheterization assemblies and kits employ hydrophilic catheters that are self-lubricating when wetted with a fluid (e.g., water) prior to use. U.S. Pat. No. 6,409,717 (Astra Aktiebolag) and U.S. Pat. No. 6,736,805 (AstraZeneca AB) describe apparatus for wetting a hydrophilic urinary catheter, comprising a wetting receptacle which defines a wetting fluid receiving area for receiving the catheter and a wetting fluid container having a discharge outlet movable from a closed position to an open position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the container. U.S. Pat. No. 6,634,498 (Coloplast A/S) describes certain urinary catheter assemblies including a urinary catheter having at least a part of its surface a hydrophilic surface layer intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium during manufacture of the catheter assembly, and a catheter package having a cavity for accommodation of the catheter. The package includes a compartment having walls of a gas impermeable material that accommodates the liquid swelling medium, and a pre-treated catheter for long term preservation of the low-friction surface character and provision of a ready-to-use catheter assembly.

[0012] Some of the aforementioned catheter devices include a protective sheath that surrounds the catheter. Such a protective sheath may serve multiple purposes. For instance, the sheath may prevent contamination of catheter as the catheter is handled prior to and/or during use. In addition, in some hydrophilic catheters, the sheath may serve to contain a wetting agent used to lubricate the catheter during use. However, certain of the aforementioned catheter devices are intended for intermittent or short-term catheterizations and may not work adequately for long-term or extended catheterizations.

[0013] Accordingly, there remains a need for an easy-to-use, sanitary and disposable catheterization assembly for extended or long-term catheterizations.